



Agency Priority Goal Action Plan

Kidney Care

Goal Leader:

Nick Uehlecke, Advisor, Immediate Office of the Secretary

Deputy Goal Leader:

Kumiko Lippold, Office of the Assistant Secretary for Health

Overview

Goal Statement: Reduce morbidity and mortality associated with end-stage renal disease and increase patient choice by improving access to alternatives to center-based dialysis. Starting from the baseline for the calendar year ending December 31, 2019, by December 31, 2021:

- Increase by 10 percent the number of new end-stage renal disease patients on home dialysis.
- Increase by 10 percent the number of kidney transplants performed.

Overview

Challenge

- There is no better example of an area that needs transformation than the way we prevent and treat kidney disease. Approximately 37 million Americans have kidney disease, and, in 2017 kidney disease was the ninth-leading cause of death in the United States. The primary form of treatment for kidney failure is dialysis, which is one of the most burdensome, draining long-term treatments modern medicine has to offer.

Opportunity

- A system that pays for kidney health, rather than kidney sickness, would produce much better outcomes, often at a lower cost, for millions of Americans.

Leadership

Goal and Deputy Goal Leader:

- Immediate Office of the Secretary (IOS)

Goal Team:

- Assistant Secretary for Planning and Evaluation (ASPE)
- Assistant Secretary for Preparedness and Response (ASPR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office for Civil Rights (OCR)

Goal Structure & Strategies

More information on HHS's strategies for this APG can be found in the Department's plan for [Advancing American Kidney Health](#):

- Reduce the risk of kidney failure
- Improve access to and quality of person-centered treatment options
- Increase access to kidney transplants

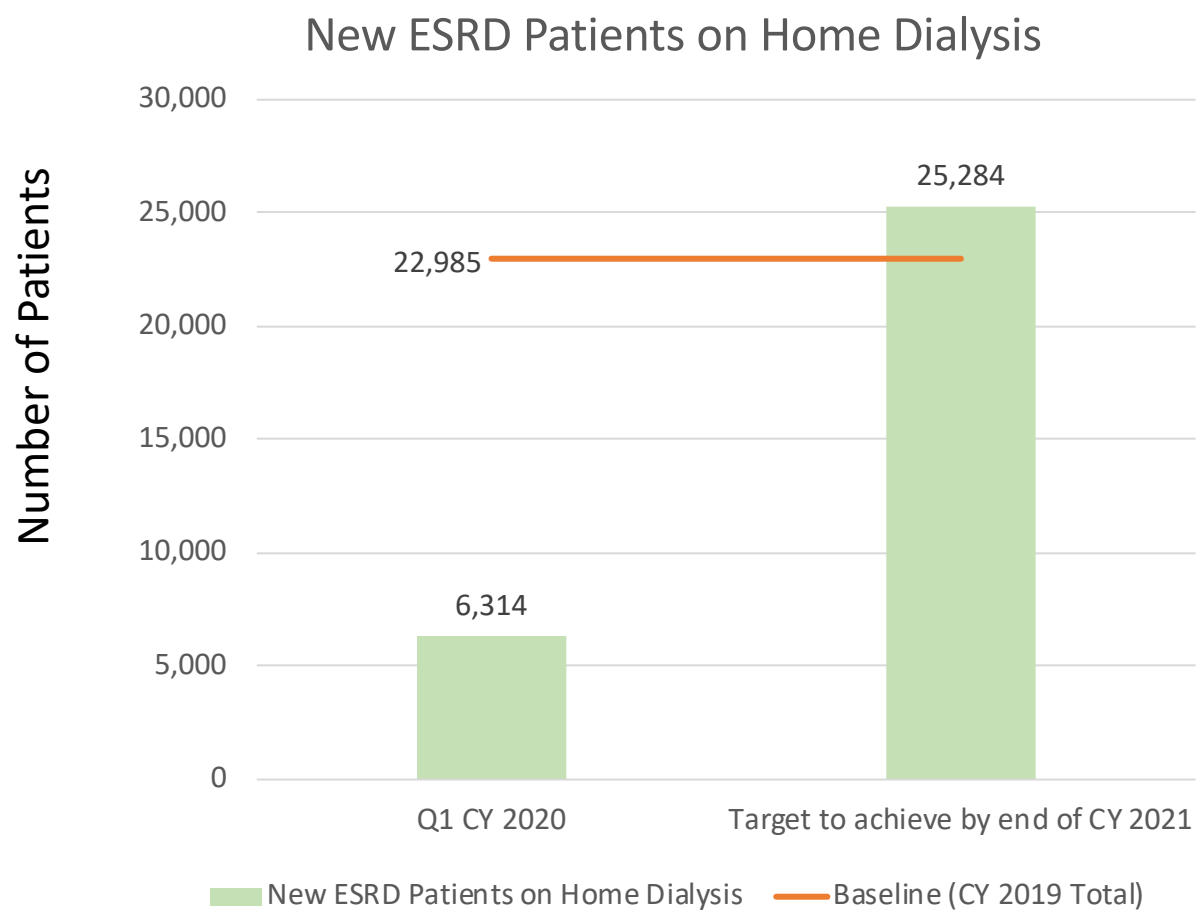
Key Indicators: Q1 Calendar Year 2020

Indicator Name	Target	Q1 CY 2020 Result*	Comments
Increase by 10 percent the number of new end-stage renal disease (ESRD) patients on home dialysis.	25,284 Patients in CY 2021	6,314, which is 25 percent of the target	The 6,314 new ESRD patients on home dialysis in Q1 CY 2020 represents 20.3 percent of all Q1 CY 2020 new ESRD incident patients.** Target may be revised once COVID-19 impact is known.
Increase by 10 percent the number of kidney transplants performed.	25,741 Transplants in CY 2021	6,135, which is 24 percent of the target	

**HHS is reporting progress for this APG on a Calendar Year (CY) cycle. This APG uses a CY 2019 baseline, and Q1 represents progress for January-March 2020. For comparison with the preceding quarter, in October-December 2019, the number of new ESRD patients starting on home dialysis was 6,330 patients (19.3% of incident ESRD patients), and the number of kidney transplants performed (both living and deceased donors) was 6,136.*

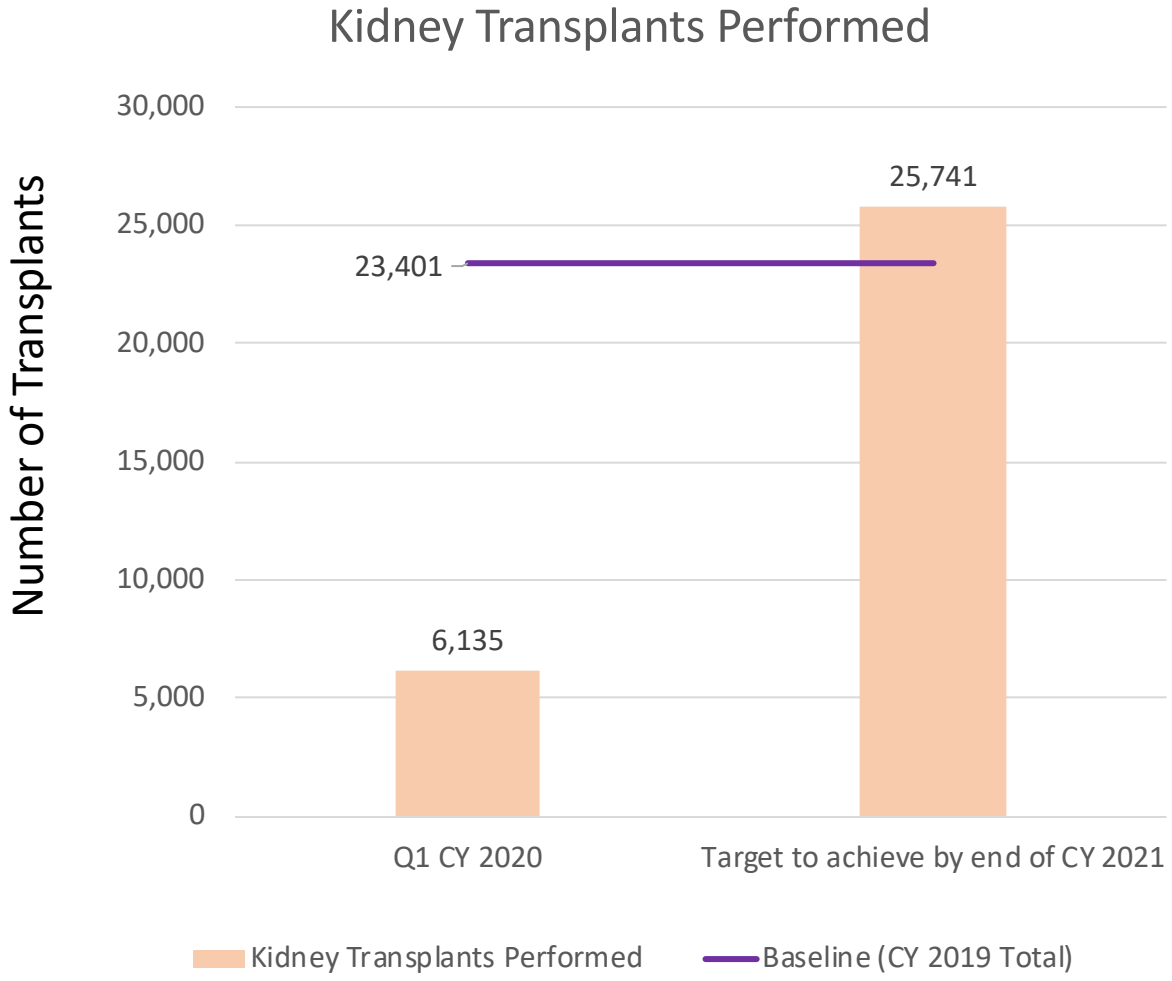
***Incident patients are new patients with ESRD in contrast to prevalent patients, which are all of the patients with the condition, which include those who developed ESRD in preceding years.*

Key Indicators: Q1 Calendar Year 2020



The Q1 CY 2020 results (6,314 new end-stage renal disease patients on home dialysis) are displayed relative to the Baseline (CY 2019) and the Target to achieve by end of CY 2021. The CY 2019 baseline reflects all new ESRD patients for the year.

Key Indicators: Q1 Calendar Year 2020



The Q1 CY 2020 results (6,135 kidney transplants performed) are displayed relative to the Baseline (CY 2019) and the Target to achieve by end of CY 2021. The baseline is larger than the Q1 CY 2020 result, because it includes all four quarters in the year.

Background - Q4 Calendar Year 2019

- In December 2019, HRSA published a [Notice of Proposed Rulemaking](#) that proposes to expand the scope of reimbursable expenses incurred by living organ donors to include lost wages and child-care and elder-care expenses.
- In 2019, IHS observed improvements in diabetes-care measures among IHS patients with diabetes. For example, Controlled Blood Pressure (<140/90) improved from 55.6 percent in 2018 to 57.2 percent in 2019; and Nephropathy Assessments were 44.2 percent in 2018 and 44.0 percent in 2019. For patients with diabetes, control of blood sugar and blood pressure, along with regular monitoring of kidney function are important to help prevent kidney failure.
- ASPR has procured 50 portable dialysis platforms in order to provide care to patients near their homes when disaster strikes. These platforms, which are FDA-approved to turn tap water into dialysate, have been procured and integrated into ASPR's Strategic National Stockpile and will be made available when requested by State and Local authorities during disaster responses.

Background - Q4 Calendar Year 2019

- In 2019, OCR favorably resolved a [complaint against the University of North Carolina system \(UNC Health Care\)](#) alleging that UNC Health Care unlawfully denied an individual with an intellectual disability the opportunity to be placed on the United Network for Organ Sharing (UNOS) transplant list on the basis of disability. UNC Health Care agreed to amend the medical records to clarify that the individual was eligible to be considered for placement on the UNOS list.

Summary of Progress: Q1 Calendar Year 2020

- Revised Public Health Service (PHS) guidance to be published in 2020 will offer a comprehensive approach to protecting solid organ transplant patients from HIV, hepatitis B, and hepatitis C. CDC is developing education and communication materials including patient and provider fact sheets, to release coinciding with the publication of the revised PHS Guideline.
- In March 2020, HRSA published a Federal Register notice proposing to amend the Eligibility Guidelines for the National Living Donor Assistance Program. The change proposes to increase the program's eligibility threshold and allow altruistic living organ donors to be eligible to participate. The changes aim to increase the overall number of living organ donors and ultimately increase the number of transplants.
- IHS continues to monitor diabetes-care measures among IHS patients. For people with diabetes, control of blood sugar and blood pressure, along with regular monitoring of kidney function are important to help prevent kidney failure.
- IHS is working to publish an article on kidney care data among American Indians and Alaska Natives.

Key Milestones

Information about the Key Milestones for this APG can be found in HHS's plan for [Advancing American Kidney Health](#).

Milestone Summary				
Key Milestone	Milestone Due Date	Status	Owner	Comments
Publish Notice of Special Interest (NOSI): Next-Generation Approaches to Renal Replacement Therapy Including Vascular Access	Q4, CY 2019	Complete	NIH	This NOSI invites small business grant applications in these areas.
Submit revised 2020 Office of Health and Safety Guideline for HHS clearance	Q1, CY 2020	Complete	OASH	The Public Health Service Guideline was cleared by HHS and released to MMWR for publication.
Publish 2020 Public Health Service Guideline	Q2, CY 2020	On-Track	OASH	
Establish an inventory of portable dialysis technologies to treat frail populations during disasters	Q2, CY 2020	Complete	ASPR	Portable dialysis technology on contract and available in the Strategic National Stockpile inventory for deployment
Establish a training capability for disaster response personnel to provide care in disaster settings	Q2, CY 2020	On-Track	ASPR	Initial training with NDMS occurred in December 2019
Kidney Accelerated Placement Project	Q3, CY 2020	On-Track	HRSA	A one-year pilot
Center for Medicare and Medicaid Innovation Kidney Care Choices Model	Q1, CY 2021	On-Track	CMS	

Data Accuracy and Reliability

To report this APG, HHS is tracking several data sets. HHS uses the ESRD National Coordinating Center's (NCC) mortality data from CROWNWeb. These data include mortality for patients in the first 90 days and in first year after dialysis initiation. For this APG, the NCC will conduct internal quality assurance on these data before providing them to HHS on a quarterly basis.

HHS uses incident dialysis modality utilization rates for dialysis on home therapy collected through CROWNWeb. This data includes dialysis modality as well as patient characteristics including time of dialysis initiation.

“New ESRD Patients” starting on a home modality is defined as patients that are dialyzing via Peritoneal Dialysis or Home Hemodialysis within 180 days of dialysis initiation.

NCC collects these data and Numerator/denominator flags are calculated using SQL code that has been independently coded by two analysts. Raw data are imported into SAS by a third analyst to create summary tables for delivery to CMS. Final results tables undergo a final round of review by a fourth team member before delivery.

For information on kidney transplants, HHS reports data from the Organ Procurement and Transplantation Network (OPTN). Transplant hospitals and organ procurement organizations are required to submit transplant-related data to the OPTN according to the OPTN Final Rule (FR 121.11(b)(2)) and OPTN data submission policies. The OPTN database includes all records of candidates ever added to the waiting list for transplant as well as all deceased and living donor transplants that have occurred since October 1, 1987. The OPTN database represents the single source of this information. Authorized users at OPTN member institutions attest that the data they enter are accurate, timely, and complete to the best of their knowledge, information and belief; and that the data are based upon information contained in corresponding medical records and other source documents, or where appropriate, are based upon clinical observation. HHS receives final reports of OPTN data three months after the close of the quarter. In the interim, HHS will report the preliminary OPTN data it has received and provide an update once the OPTN data become final.

Stakeholder / Congressional Consultations

HHS's activities for this APG are part of the Department's approach for implementing the Advancing American Kidney Health Initiative. Coordination with Congress has been continual over the course of the initiative.

As part of its ongoing commitment to ensure that health care entities provide organ transplant services in a nondiscriminatory manner consistent with federal civil rights laws, OCR continues to organize listening sessions with advocacy organizations and other HHS components to discuss discriminatory practices in organ transplantation.